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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/868,195	09/14/2001	Martin John Glenton Hughes	GJE-71	7256

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EXAMINER

DUFFY, PATRICIA ANN

ART UNIT PAPER NUMBER

1645

DATE MAILED: 04/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/868,195

Applicant(s)

HUGHES ET AL.

Examiner

Patricia A. Duffy

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 January 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 45, 47 and 50-53 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 45 and 47 is/are allowed.
- 6) ☒ Claim(s) 50-53 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

RESPONSE TO AMENDMENT

The amendment filed 1-31-06 has been entered into the record. Claims 1-44, 46 and 48-49 have been cancelled. Claims 45, 47 and 50-53 are pending. Claims 50-53 are under examination. Claims 50-53 are under examination.

The text of Title 35 of the U.S. Code not reiterated herein can be found in the previous office action.

Rejections Withdrawn

The rejection of claims 25, 27, 28, 32, 36 and 48-51 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement is withdrawn in view of the amendment to the claims or cancellation of the claims.

The rejection of claims 50 and 51 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in view of the amendments to the claims.

New Rejections Based on Amendment

Claims 50-53 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

The claims are drawn to a method for *raising antibodies* against Group B *Streptococcus in a neonate* by immunization prior to or during pregnancy. It is noted that the claims are viewed as specifically requiring that the antibodies be raised in the neonate. This recitation is seen to require active immunization of the neonate by administered

isolated Group B *Streptococcal*/non-phosphorylating NADP-dependent glyceraldehydes-3-phosphate dehydrogenase. The teachings of the specification are limited to contemplation that "the vaccine may be administered to females either prior to or during pregnancy to protect mother and neonate against infection by GBS.". This passage as read by the skilled artisan, contemplates passive transfer of maternal antibodies to the fetus and neonate by active immunization of the mother. This does not provide conception active immunization of the neonate as indicated by the preamble phrase "raising antibodies in a neonate". It is well known in the immunological arts that certain classes of antibodies are able to traverse the placenta and may passively immunize the fetus after the third month. The art is completely silent on the ability of any fetus or neonate to have the ability to raise antibodies when the antigen is administered indirectly the mother either prior to or during pregnancy. The art generally teaches that neonates have undeveloped immune systems and have difficulty in generating immune responses (see abstract Hassett et al, Journal of Virology, 71(10):7881-7888, 1997). The art is silent on the ability of the fetus to raise an active immune response.

Further, the claims as currently structured, require that the neonate be actively vaccinated by administering the vaccine to the mother prior to or during the pregnancy. There is no contemplation of active vaccination of the fetus or neonate by the specification as originally filed. Additionally, a neonate is a newborn baby up to one month old (see Stedman's Medical Dictionary on line) and as such a patient cannot be administered a vaccine during pregnancy with a neonate. Further, the passage would not convey active immunization of the neonate by immunization of the mother prior to or during the pregnancy, because this concept contradicts all the current knowledge of maternal/fetal barrier and passive transfer of maternal immunity. The cells producing maternal antibodies are not transferred during pregnancy, therefore maternal antibodies cannot be raised in the neonate. Only certain classes of antibodies can cross the placenta to the fetus. Post birth, only certain classes of antibodies are secreted in maternal milk.

The only antibodies that are "raised in" a neonate are that which are a result of natural infection or active immunization. As such, one skilled in the art would not recognize that the instant claims do not have conception by way of written description in the specification as filed.

Status of Claims

Claims 45 and 47 are allowable. Claims 50-53 stand rejected.

Conclusion

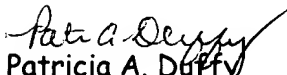
Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia A. Duffy whose telephone number is 571-272-0855. The examiner can generally be reached on M-Th 6:30 am - 6:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on 571-272-0864.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.


Patricia A. Duffy

Primary Examiner

Art Unit 1645